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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,336	03/23/2004	Jacques Jolivet	PHARMA-357	2203

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EXAMINER
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DELACROIX MUIRHE, CYBILLE

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/806,336

Applicant(s)

JOLIVET ET AL.

Examiner

Cybille Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2005 and 21 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-15 and 17-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-15 and 17-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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***Detailed Action***

1. Claim 47 (58) are rejected under 35 U.S.C. 102(a) as being anticipated by Leblond et al. (abstract #2633).
2. Claims 1, 3-15, 17-46 and (48-57) are rejected under 35 U.S.C. 103(a) as being unpatentable over Gourdeau et al., 6,747,036 in view of Chu et al., 5,817,667 and LeBlond et al. (#2633).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New claims 48-60 are rejected for reasons already of record in the office action mailed April 8, 2005. Specifically, new claims 48-57 and claim 58 introduce limitations, which have been previously addressed in the prior art rejections listed above. See paragraphs 5-6 of the office action mailed April 8, 2005.

New claims 59-60 are addressed below in a new ground(s) of rejection that is necessitated by applicant's amendment.

***Response to Amendment(s)***

The following is responsive to applicant's amendment, declarations under 37 CFR 1.132 and remarks received Oct. 11, 2005 and Feb. 21, 2006.

Claims 2, 16 are cancelled. New claims 48-60 are added. Claims 1, 3-15, 17-60 are currently pending.

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The previous claim objections set forth in paragraphs 1-2 of the office action mailed April 8, 2005 are withdrawn in view of applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 112, first paragraph (scope of enablement), set forth in paragraph 3 of the office action mailed April 8, 2005, is withdrawn in view of applicant's amendment and the remarks contained therein.

The previous claim rejections under 35 USC 112, second paragraph, set forth in paragraph 4 of the office action mailed April 8, 2005, are withdrawn in view of applicant's amendment and the remarks contained therein.

However, applicant's arguments and declarations traversing the previous claim rejection under 35 USC 102(a) over Leblond et al. (abstract #2633) and the previous claim rejection under 35 USC 103(a) over Gourdeau et al., 6,747,036 in view of Chu et al., 5,817,667 and LeBlond et al. (#2633) (see paragraphs 5-6 of the office action mailed April 8, 2005) have been considered but are not found to be persuasive.

The declarations under 37 CFR 1.132 filed Oct. 11, 2005 are insufficient to overcome the rejection of claims 1, 3-15, 17-46 47 and (48-58) based upon 35 USC 102(a) and 35 USC 103(a) as set forth in the last Office action because: of reasons provided below.

Said rejections are maintained essentially for the reasons given previously in the office action mailed April 8, 2005 with the following additional comment.

Applicant argues that the LeBlond et al. abstract lists 11 co-authors, including the two inventors. Pursuant to *In re Katz*, applicants submit two declarations under 37 CFR 1.132 by both inventors. In both declarations, applicants aver that, to the extent the claimed invention is

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disclosed in these publications, such disclosure is the invention of Jacques-Jolivet and Henriette Gourdeau. The remaining authors listed on the abstract are not inventors and contributed to aspects, which were not part of the conception of the subject matter of the claims of the instant application. Applicant's conclude by stating the subsequent to the filing of the two declarations, it was determined that there is an error in the text. In both declarations, applicants refer to a study done on rats. However, the study mentioned in the abstract was done on mice. Therefore, applicants will submit corrected declarations in the near future.

Said arguments have been considered but are not found to be persuasive.

While both declarations were considered in their current form, the issue of whether the study was performed on rats or mice has yet to be rectified. That is to say the declarations are technically deficient. Submission of corrected declarations would remove the rejection of claims 1, 3-15, 17-46 47 and (48-58) based upon 35 USC 102(a) and 35 USC 103(a) as set forth in the last Office action. Until then, the rejections are respectfully maintained.

***New Ground(s) of Rejection***

***Claim Rejection(s)—35 USC 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 59-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over LeBlond et al. abstract (see office action mailed April 2005) in view of Chu et al., 5,817,667 (already of record).

LeBlond et al. as applied in paragraph 5 of the office action mailed April 8, 2005.

LeBlond et al. do not disclose administering an additional chemotherapeutic agent as required by claims 59 and 60. Yet, the examiner refers to Chu et al., which teach a method of treating cancers such as a colorectal cancer, the method comprising administering (intravenously) an effective amount of (-)-OddC, i.e. troxacitabine, or a salt thereof to a patient in need thereof. Chu et al. additionally disclose that (-)-OddC can also be administered in combination with other known anticancer agents. Please see col. 3, lines 10-52; col. 10, lines 54-61.

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of LeBlond et al. to combine troxycitabine with another chemotherapeutic agent because Chu et al. suggest that troxycitabine combined with additional agents would generally be more effective in treating cancer. Thus, one of ordinary skill in the art would reasonably expect the additive effect of the combination of agents to be effective in treating the colon cancer.

### ***Conclusion***

Claims 1, 3-15, 17-60 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybillie Delacroix-Muirheid** whose telephone number is **571-**

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**272-0572.** The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM   
April 26, 2006

  
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